REMARKS

Applicants respectfully request reconsideration of the present application in view of the following remarks.

Claims 1-10, 13-29, and 31-37 are pending. Claims 1-10 and 36 are rejected as being unpatentable under 35 U.S.C. §103 based upon a combination of Cho in view of Bosley, Hibbs, Hobbs, and Sarkis. Applicants respectfully traverse.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. 103(a) (Supp. 1998); see Graham v. John Deere Co., 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See Graham, 383 U.S. at 17-18, 148 USPQ at 467.

In the previous communication, applicants pointed out that there is no dispute that the primary reference Cho, while disclosing a guide catheter, fails to disclose several limitations of claim 1. For example, absent is a distal tip that is both radio-opaque and echogenic by reason of the specified tungsten carbide particles that are distributed within a polymeric material. Bosley, therefore, is relied upon for its disclosure of a device that is both ultrasonically imageable and radiographically imageable. However, Bosley is mischaracterized in the stated rejection as to how radiopacity and echogenicity are obtained. Bosley is characterized as having a base material “mixed with tungsten spheres so that the entire tube is radiopaque and echogenic.” That is incorrect.

Applicants pointed out that the Bosley reference is deficient in disclosing a medical device having a material structure that is both ultrasonically and radiographically imageable by reason of the use of *tungsten particles*. Instead, Bosley teaches the use of glass spheres for echogenicity and inclusion of finely ground tungsten powder to provide radiopacity. See Bosley at col. 5, line 66 to col. 6, line 5; col. 6, lines 26-34; col. 11, lines 30-34:

> The sound reflective particles 127 are embedded in matrix material 125. Particles 127 are preferably made of a hard material, and it has been found that *small glass particles* are especially well suited for this application. Specifically, glass particles having a generally spherical shape forming *glass microspheres* are very suitable.
>
> Optionally, but not necessarily, radiopaque material 528 may also be mixed with the matrix material and the sound reflective particles. The radiopaque material may be one of numerous radiopaque materials already known, as for example, barium, bismuth or tungsten. The radiopacifier may be *finely ground powder* mixed during the mixing step 533.

Bosley, therefore, discloses a composite matrix material that consists of polyethylene having sound reflective particles in the form of 5 micron (i.e., 5000 nanometers) diameter glass microspheres embedded therein for echogenicity (col. 4, lines 7-17). Bosley separately includes a radiopaque material such as tungsten powder to provide imaging with radiographic equipment (col. 4, lines 20-23). Bosley, however, fails to teach, as posed by the rejection, use of a particular tungsten material structure to provide both echogenicity and radiopacity. The disclosure in Bosley is incorrectly characterized and applied in the rejection.

Accordingly, applicants argued that the conclusion necessarily drawn is that it would not have been obvious to include tungsten *particles* of not more than 500 nanometers and 70 to 75 percent by weight in the sheath of Cho based upon Bosley. Instead, following Bosley necessarily results in Cho having a sheath containing both 5 micron glass spheres and tungsten powder. The stated rejection is, therefore, based on a mischaracterization of the disclosure of Bosley. As such, the scope and content of the prior art is mischaracterized and inaccurate. Under Graham v. Deere, the rejection is therefore flawed, without merit, and should be withdrawn.

In the final office action, the Examiner's response completely side steps applicants' arguments and the clear insufficiency of the stated obviousness rejection based on Bosley. The Examiner apparently miscomprehends applicants' argument as being a contention that Bosley does not disclose tungsten particles. The Examiner fails to understand that the flaw in the combination based on Bosley is that, without the inclusion of glass spheres and the use of only tungsten powder, the Bosley material is not both "radiopaque and echogenic." Thus, combining Bosley with Cho necessarily results in a device having a sheath containing *both* 5 micron glass spheres and tungsten powder.

The Examiner skips over this "misfit" between Cho/Bosley and the claimed subject matter to go directly to the tungsten particles concentration by weight limitation of the claims and cites to Hobbs. The disclosure of Hobbs provides for the use of tungsten powder embedded in a PEBA copolymer of a soft tip catheter. The tungsten powder in Hobbs, while being 70 percent by weight, however, has a mean average diameter of 1 to 2 microns (i.e., 1000 to 2000 nanometers). But, more importantly, Hobbs provides only radiopacity; echogenicity is nowhere considered in Hobbs.

As a consequence of Hobbs disclosing 1-2 micron tungsten particles, the Examiner is forced to resort to Sarkis, which is yet further "stacked" on top of Cho/Bosley/Hobbs. Sarkis, while indicating an echogenic material having particles of average size less than 500 nanometers, also specifies that the particles are 2% to 40% by weight (col. 6, lines 6-9). Moreover, Sarkis, like Bosley, has a separate radiopaque material in addition to the echogenic material (col. 5, lines 52-56). Most importantly, Sarkis directs its teachings to materials having a specific gravity of 5 or greater, which includes various oxides, particularly iron oxide and zinc oxide. Sarkis does not concern tungsten particles. Tungsten has a specific gravity of 19, and tungsten carbide has a specific gravity of 14. Thus, Sarkis provides no teachings that are relevant to Hobbs. Moreover, Sarkis underscores the teaching in Bosley of using one material for echogenicity and another, separate material for radiopacity.

Hibbs is relied only upon in regard to its teachings concerning hardness parameters of devices in certain applications. Hibbs does not address the shortcomings of Bosley, of Hobbs, and of Sarkis.

The requisite combination of limitations of claim 1, as a whole, remains unmet by the scope and content of the prior art combination of Cho/Bosley/Hobbs/Sarkis/Hibbs relied upon in the obviousness rejection advanced in the office action. The final office action cloaks this combination of prior art as a body of knowledge that a person of ordinary skill in the art “has good reason to pursue [as] the known options within his or her technical grasp.” However, what results from following these “options” does not yield the claimed subject matter. Instead, by following the ”options” represented by Cho, Bosley, Hobbs and Sarkis, a device results that is both ultrasonically imageable and radiographically imageable by reason of inclusion of an echogenic material (glass spheres or iron oxide/zinc oxide particles) and a separate radiopaque material of tungsten powder with 1-2 micron sized particles. That is not the claimed subject matter. Pursuing the “known options” available as represented by the combination of prior art advanced in the office action does not yield the success of the claimed subject matter.

Because assembling a device in accordance with the combination of teachings, as properly characterized and present, in Cho, Bosley, Hobbs, Hibbs and Sarkis does not result in the claimed subject matter, as a whole, of the present invention. The obviousness rejections cannot stand.

Claims 13, 14, 23, 24, 31-35, and 37 were rejected as being obvious over the same combination of references as applied to claim 1 and further in view of Wijayarathna. Given the failure of the combination of references applied against claim 1 to present a meritorious obviousness rejection, the rejection of claims 13, 14, 23, 24, 31-35, and 37 must also necessarily fail as well.

In summary, each rejection of the claims is based upon an erroneous analysis under *Graham* that is without sufficient basis in the scope and content of the prior art to result in the claimed subject matter as a whole. Withdrawal of the rejections and issuance of a Notice of Allowance is warranted based upon the amended claims and the remarks.

Finally, if there are any formal matters remaining, the Examiner is requested to telephone the undersigned attorney to attend to those matters.

Respectfully submitted,

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Date

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